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09/800,014

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Chad Stephen Gephart

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01/29/2004

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ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103-7013

EXAMINER

OLSEN, KAJ K

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,014

Applicant(s)

GEPHART ET AL.

eb

Examiner

Kaj Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 21 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 21, and 24-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-12, 17, 18, 21, 24, 26-28, 30 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks (USP 5,096,669) in view of Ozawa (USP 5,690,893).
 1. Lauks disclosed all the limitations of the set forth system (see prior rejection), but did not explicitly set forth a reader for the indicia or a barcode. Ozawa teaches in an alternate electrochemical system that other indicia for identifying details about the particular test cell being manipulated. Those other indicia include bar codes and programmable memory (col. 1, lines 18-23 and col. 5, line 59 through col. 6, line 14). These other means of indicating to the instrument details about the particular test cell allow one to provide more information than is possible with the notches of Lauks including correction and calibration factors, and sensor lot numbers. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Ozawa for the system of Lauks in order to further improve the measurement accuracy of the individual sensors. With respect to having every identification information being unique, if the information contained calibration or correction information unique to that particular test cell, then every identification information would be unique.
 2. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks and Ozawa in further view of Tomita (USP 4,797,188).

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3. Lauks and Ozawa teach all the limitations of the claims, but do not explicitly provide the detailed structure for the test cell. Tomita teaches in an alternate cell for monitoring the constituents in aqueous samples that a typical test cell for measuring concentrations of things such as potassium includes an electrolyte (i.e. an internal solution) 19 coated over one of the electrodes (fig. 1). Internal solutions are a well established means for ensuring appropriate electrochemical contact between the metal electrode and the sample and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Tomita for the system of Lauks and Ozawa in order to ensure appropriate electrochemical contact between the metal electrode and the sample. Tomita also teaches the use of a gelled form of the internal solution as well as an ion selective membrane 20 which has been impregnated with an appropriate chemical species over that gelled solution (col. 4, line 62 through col. 5, line 38).

4. Claims 25 and 29 (and claims 27 and 28 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks and Ozawa in further view of Jakubowicz et al (USP 4,798,705).

5. Lauks and Ozawa set forth all the limitations of the claims, but did not explicitly set forth the use of either a liquid crystal display or a thermal printer. Jakubowicz discloses that both those forms displays and printers are well known in the analytical art (col. 3, lines 3-6). With respect to claims 27 and 28 in the alternative), Jakubowicz also shows that the printer and keyboard of a system can be integrated into the instrument (fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks and Ozawa because the substitution of one known means

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for display or printer for another known means requires only routine skill in the art.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks and Ozawa because integrating the keyboard and printer into the single device simplifies the system making it easier to handle.

6. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks and Ozawa in further view of Betts et al (USP 5,405,510).

7. Lauks and Ozawa set forth all the limitations of the claims, but did not explicitly identify the use of the RS 232 interface or the use of an internal power source. Betts discloses that both that particular interface as well as the use of batteries is well known in the art (col. 14, lines 6-9 and col. 19, lines 15-18). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Betts for the system of Lauks because the use of standard interfaces and power sources requires only routine skill in the art. With respect to the batteries being rechargeable, rechargeable batteries are an obvious and conventional form of battery and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize them because they would save the system operator money over the long term.

Response to Arguments

8. Applicant's arguments filed 11-3-2003 have been fully considered but they are not persuasive. Although applicant is correct about the fact that neither Lauks nor Tomita teach the presence of the set forth indicia, this point is moot in view of both this and the previous art

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rejection. The examiner has never suggested that Lauks and Tomita set forth the claimed indicia.

The teaching of the indicia was the purpose of the secondary teaching of Ozawa.

9. With respect to the rejections utilizing Ozawa, applicant urges that there is no suggestion in Ozawa that the indicia (i.e. bar code) would be read by the instrument prior to insertion of the reagent vessel. First, the examiner questions where amended claim 1 actually requires the system be configured for reading the bar code prior to insertion. Amended claim 1 merely states that the instrument include "a reader for reading the indicia...prior to engagement". The use of "prior" here is the intended use of the reader. If the prior art renders obvious the reader for reading the indicia, then when that reader actually reads that information is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. Second, even if the examiner were to give the "prior" due consideration, reading the bar code of Ozawa prior to insertion would have been an obvious time to do so. In particular, one of the items of information suggested for storing on the bar code of Ozawa is the kind of reagent on the reagent vessel (col. 1, lines 18-23). As the applicant is presumably aware of, the type of reagent utilized for the sensor of Lauks would impact how the analyzer processes the electroanalytical information and that information would have been needed prior to any analysis (e.g. prior to insertion). In addition, any calibration information would have been necessary prior to the insertion as well.

10. Applicant also questions the examiner's referencing of col. 5, line 59 through col. 6, line 14 because there is nothing to suggest that this additional information would be put on the bar code. The examiner didn't say that this information would be placed on the bar code. Rather the examiner was saying that the programmable memory of Ozawa read on the applicant's broadly

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defined "indicia" (i.e. the programmable memory of Ozawa was an indicating means in the analogous way that a bar code is an indicating means). Except in the claims explicitly specifying a bar code, there is nothing in the claim to suggest that the indicia must be visually read. In addition, the list of things that can be stored on the bar code is open ended (see the "and so forth" of col. 1, line 22). One possessing ordinary skill in the art would recognize that some of the information listed in col. 5 and 6 of Ozawa (e.g. calibration information) could also have been placed on the bar code of the reagent vessel to provide further information about the cell.

11. Applicant also urges that there is nothing in Ozawa that suggests the indicia on a particular test cell is "unique" for that test cell. First, the examiner is unclear how the applicant can utilized this claim language to read free of the prior art. In particular, applicant is claiming indicia that are unique such that no two cells have the same indicia. However, applicant isn't claiming any other cells so how could one know if their indicia is different when that difference depends on some other cell that is not part of the claimed invention? This claim language seems to depend on properties (e.g. what other cells are being manufactured, how many cells are being manufactured, etc) that are outside of the purview of the actual claim. If applicant has included on their indicia a non-obvious piece of information that results in each of their indicia being unique, then the applicant is invited to claim what that non-obvious piece of information is. However, absent any clear description of what that is included on the indicia that makes it unique from any other unclaimed cell, it is not clear how applicant's indicia can read free of prior art. Second, even if the examiner were to interpret this limitation as the applicant would appear to like it to be interpreted (i.e. every cell manufactured is assigned a unique indicia separate from any other indicia) there are a number of reasons why any of the information set forth either in

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col. 1 or col. 5 and 6 of Ozawa that would result in a unique indicia for each test cell. For examiner the lot might consist of an individual sensor, the calibration information might be unique for each sensor, or the lot management information might uniquely identify each sensor individually for management purposes. Again, absent any clear definition of what is being stored on the indicia that make it unique, there are innumerable ways that the bar code or memory of Ozawa could be unique.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The

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examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (571) 272-1342.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for all official communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1300.

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long horizontal flourish extending to the right.

Kaj K. Olsen
Primary Examiner
AU 1753
January 22, 2004